



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/423,715	01/12/00	PASSMORE	C 6442/60557

JAY H MAIOLI
COOPER & DUNHAM
1185 AVENUE OF THE AMERICAS
NEW YORK NY 10036

HM12/0323

EXAMINER
BERMAN, A

ART UNIT	PAPER NUMBER
1619	

DATE MAILED: 03/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/423,715	Applicant(s) PASSMORE ET AL.	
	Examiner Alysia Berman	Art Unit 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 21-23 is/are rejected.
- 7) ☒ Claim(s) 5-20 and 24 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|---|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5,7</u> | 20) <input type="checkbox"/> Other: |

DETAILED ACTION

1. Receipt is acknowledged of the information disclosure statements filed June 9, 2000 and July 17, 2000 and the request for corrected filing receipt filed June 13, 2000. Claims 1-24 are pending.

Specification

2. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.
3. The disclosure is objected to because of the following informalities:
The specification is unclear because it is not consistent in the use of the terms "pharmacologically acceptable component" and "pharmaceutically acceptable carrier." At page 5, lines 4-9, the specification defines a pharmacologically acceptable component. Then, at page 5, lines 11-14, the specification refers to the "said pharmaceutically acceptable carrier" but there is no previous mention of this term. If Applicants intent is to disclose that the pharmacologically acceptable component and the pharmaceutically acceptable carrier are the same, it is requested that the same language be used consistently.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

Art Unit: 1619

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 3 and 4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite a pharmaceutically acceptable component but there is no mention of this component in the specification. The specification discloses a pharmacologically acceptable component and a pharmaceutically acceptable carrier.

6. Claims 1-4 and 21-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims require a pharmaceutically acceptable carrier. However, neither the specification nor the claims provides a clear and concise definition of what is encompassed by the pharmaceutically acceptable carrier. At page 8, lines 11-24, the specification refers to "[s]aid pharmaceutically acceptable carrier" but there is no previous mention of such a carrier. The specification does not define the pharmaceutically acceptable carrier. One skilled in the art would not be enabled to make the invention using a pharmaceutically acceptable carrier as instantly claimed.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-4 and 21-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claims 1-4 and 21-23 are indefinite because they require a pharmaceutically acceptable carrier. Neither the specification nor the claims provides a definition of what is encompassed by the term "pharmaceutically acceptable carrier." The metes and bounds of the claims cannot be determined.

10. The word "including" in line 6 of claim 1, line 4 of claim 21, line 3 of claim 22 and line 9 of claim 23 renders the claims indefinite. It is unclear if a eutectic mixture is a required limitation of the claims or merely an example of a preferred embodiment. Amendment of the claims substituting "comprising" for "including" would overcome this rejection.

11. The phrase "the continuous phase being provided by" in claims 1 and 21-23 renders the claims indefinite. Applicants' intent is unclear with regard to what is encompassed by the continuous phase. Amendment of the claims substituting "comprising" for "being provided by" would overcome this rejection.

12. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The

Art Unit: 1619

Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 2 recites the broad recitation "the first pharmacologically active agent has a melting point between 35 and 75° C", and the claim also recites "preferably 40-50° C" which is the narrower statement of the range/limitation. claim 2 recites the broad recitation "the second pharmacologically active agent has a melting point between -40° C and 150° C", and the claim also recites "preferably between -5° C and 90° C" which is the narrower statement of the range/limitation. claim 4 recites the broad recitation "between 40° and 150° C", and the claim also recites "preferably between 40° and 75° C" which is the narrower statement of the range/limitation.

13. Claim 23 is indefinite because it recites the step of applying a composition to an accessible body surface but does not define the body surface. Is the composition applied to the body surface of an animate object such as a human or an animal or an inanimate object such as an automobile, for example? Clarification is requested.

14. Claims 21 and 22 provides for the use of use of a topical composition, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it

merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 21 and 22 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

15. This application is replete with 35 U.S.C. 112 issues. The above are just some examples. Applicant is required to review all of the claims for 35 U.S.C. 112 issues and make appropriate corrections.

Claim Objections

16. Claims 5-20 and 24 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must refer to other claims in the alternative and cannot depend from other multiple dependent claims. See MPEP § 608.01(n). Accordingly, the claims 5-20 and 24 have not been further treated on the merits.

Correspondence


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alysia Berman whose telephone number is 703-308-


Art Unit: 1619

4638. The examiner can normally be reached on Monday through Friday from 8:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on 703-308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 or 703-305-4456 for regular communications and 703-308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234 or 703-308-1235.


Alycia Berman
Patent Examiner
March 21, 2001


DIANA DUDASH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600